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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,630	09/21/2001	Peter Knox	PA 9847	5704
36335	7590	03/10/2005	EXAMINER	
AMERSHAM HEALTH IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231			LAM, ANN Y	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/869,630	<b>Applicant(s)</b> KNOX ET AL.	
	<b>Examiner</b> Ann Y. Lam	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on December 13, 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 3, recites the limitation "said assay reagent". There is insufficient antecedent basis for this limitation in the claim. (Claims 3-9 are indefinite because they depend from claim 1, which is indefinite.)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duke-Cohan et al., 6,265,551, in view of Balamore, WO 95/27438.

Duke-Cohan et al. disclose the invention substantially as claimed.

More specifically, as to claims 1 and 10, Duke-Cohan et al. discloses an in vitro method which is a test involving a reaction of one or more biological molecules (col. 4, lines 11-18, and col. 3, lines 45-56\_ and which comprises:

labeling a biological molecule (col. 3, lines 53-54), wherein one of said one or more biological molecules comprises an assay reagent (col. 3, line 50-54);

conducting said reaction (col. 3, lines 45-46); and

observing a magnetic response resonance spectrum and/or NMR image of the label during the course of said reaction (col. 3, lines 65-66).

As to claims 3 and 4, the assay is an immunoassay or binding assay (col. 3, lines 45-46 and 50-54.)

As to claim 5, the molecule is a peptide or a protein (col. 1, lines 25-26.)

Although Duke-Cohan et al. teaches use of a radioactive label as a detectable substance (col. 3, lines 53-54 and lines 64-65), Duke-Cohan et al. however does not explicitly disclose that the label used in the NMR spectroscopy is hyperpolarized  $^{129}\text{Xe}$ .

Balamore discloses an in vitro method (see page 7, lines 20-21 and page 9, lines 26-30) comprising labeling a biological molecule with hyperpolarized  $^{129}\text{Xe}$  (see page 6, lines 12-20), and observing a change with time of a magnetic resonance spectrum (NMR) and/or NMR image of the hyperpolarized xenon in the environment of the biological molecule during the course of said reaction (see page 7, lines 6-12.)

It would have been obvious to one of ordinary skill in the art to utilize hyperpolarized  $^{129}\text{Xe}$  taught by Balamore as the detectable NMR label generally disclosed in the Duke-Cohan et al. method because Balamore teaches that it provides

the advantage as a detectable label in an in vitro biological system, such as the Duke-Cohan et al. in vitro biological assay system.

And as to claims 6-9, Duke-Cohan et al. also does not disclose that the hyperpolarized  $^{129}\text{Xe}$  is enriched at a level of 40% or more, or that the degree of hyperpolarisation is 8% or more, or that the method is performed in a solution wherein the solvent has a viscosity in the range of 700 to 1500 mPs, or that the pressure of the xenon gas is at least 5 bar.

Since these conditions are generally disclosed in Balamore and these claimed ranges appear to be the optimum or workable ranges, it would have been obvious to modify the Duke-Cohan et al. reference to provide these ranges because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum of workable ranges involves only routine skill in the art (In re Aller, 105 USPQ 233.)

### ***Response to Arguments***

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

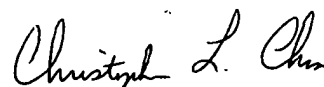
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800-1641

3/4/05